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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,216	08/16/2001	Lawrence S. Cousens	PP00037.201 2300-0037.04	3820
7590	12/09/2003		EXAMINER	
			ALLEN, MARIANNE P	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 12/09/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

S.M.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/931,216	COUSENS ET AL.	
	<b>Examiner</b> Marianne P. Allen	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 08 September 2003.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 18-28 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 18-28 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
 a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) Notice of References Cited (PTO-892)      4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) Notice of Informal Patent Application (PTO-152)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 pages.      6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 24-28 have been newly added. Claims 18-28 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Oath/Declaration***

A supplemental oath or declaration is required under 37 CFR 1.67 as set forth in the prior Office action. Applicant's response acknowledges that a new oath will be submitted.

### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The amendment to claim 18 and language in new claims 24-28 lacks antecedent basis in the specification. It is noted that this language parallels claim language in U.S. Patent 4,751,180 and the application that issued as the '180 patent is incorporated by reference into the instant specification; however, this terminology is not found in the present specification.

### ***Double Patenting***

Claims 18-28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 4,751,180 for the reasons set forth in the prior Office action. The new limitations in claim 18 are found in claims 12-17 of the '180 and it would have been obvious to use these DNA sequences in the method of claims 1-11.

Applicant acknowledged this rejection in their response.

***Claim Rejections - 35 USC § 102***

Claims 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Hallewall et al. (U.S. Patent No. 5,252,476).

Hallewall et al. discloses production of human superoxide dismutase fused to additional amino acids (for example a heterologous secretory signal sequence) in a variety of host cells including yeast, *E. coli* and *B. subtilis*. See abstract; claims; columns 2-3; column 6, line 51, through column 7, line 2. Such a heterologous secretory signal sequence would meet the limitation of a selectively cleavable link wherein said link provides for a selectively cleavable site.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

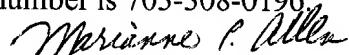
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1631

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Marianne P. Allen  
Primary Examiner  
Art Unit 1631

mpa